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WORKMAN NYDEGGER
1000 EAGLE GATE TOWER,
60 EAST SOUTH TEMPLE
SALT LAKE CITY, UT 84111

| EXAMINER | |
|---|---|
| PELLEGRINO, BRIAN E | |
| **ART UNIT** | **PAPER NUMBER** |
| 3738 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/652,498 | VON OEPEN, RANDOLF | |
| | Examiner | Art Unit | |
| | Brian E. Pellegrino | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,8,10,16,21,23,24 and 30-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8,10,16,21,23,24 and 30-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/2/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the catheter having "a single expandable balloon" and "a single substantially uniformly cylindrical deformable stent" was not found in the written disclosure. Without a clear description of the features of the invention, it is difficult to determine the scope of the invention. Applicant is reminded that claims are interpreted in light of the specification and when interpreting claims, one looks to the specification to determine what the scope of the claims embrace. In this instance no explanation was provided for the balloon or the stent.

### *Claim Objections*

Claims 31,36,37 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitation of "first and second fixing portions with a middle portion having a smaller diameter than a diameter of the fixing portions and tapered portions" has already been recited or implied by claim 30 from which it depends, see lines 16-26 of claim 30. Adding such a limitation is a double inclusion and improper.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3,8,10,16,21,23,24 and 30-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 30 recite a "single substantially uniformly cylindrical deformable stent". In the art of stents, there are numerous constructions that one can use to form the support structure. However, the Applicant's **specification** provides absolutely no guidance or standard for making the structure to enable one of ordinary skill in the art to ascertain the scope of the terminology. The specification does not use the terminology of "single substantially uniformly cylindrical deformable stent" and while the figures 1,2 show an embodiment of a stent, it does not provide a basis for the written requirement standard in determining the scope of a claim. The addition of the terms "single" and "uniformly" which do not appear in the specification as filed, introduce new concepts and hence violate the description requirement of the first paragraph of Section 112. For example, while the Applicant's *drawing* may illustrate a single mesh or woven wire uniform type stent, it does not provide support for other constructions of stents that may embrace a "single"

stent or “uniform” stent. The failure to describe terms of a claim must be considered to lack support since one of ordinary skill can not determine what one would consider a “single” and “uniformly” deformable stent based on general knowledge of ordinary stent constructions. For example various constructions can be combined to form a single stent, see for example 5,383,892. Thus, would the Cardon construction be considered a “single” and "uniformly” deformable stent? Maybe, maybe not, but without the specification defining what the Applicant meant, there is no support for such limits imposed in the claims. Additionally, in claims 1 and 30, introduce further new matter in reciting a “single expandable balloon” because this also precludes structures embraced by the scope of the claim. For example, while the drawings (Figs. 1,2) show what may appear as a “single” balloon, the written description failed to explain whether a catheter can be constructed with multiple balloons having the claimed configuration. See for example cited reference to Stack (EP 714640) which has multiple stents on multiple balloons of a catheter. Applicant’s specification did not recite whether the balloon was "single" or that the catheter required only a "single" balloon, and thus such a limitation adds new matter.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,30-32,36,37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glastra et al. (EP 0779062) in view of Lunn (5476506). Glastra et al. disclose (Fig.

5) a single substantially uniformly cylindrical deformable stent **24**. Glastra et al. further disclose (Fig. 6) a catheter with a single expandable balloon **26**. In addition Glastra discloses (Fig. 3) the balloon **6** can be designed with first and second **substantially** cylindrical end sections having an outer diameter and being expandable to engage an interior vessel wall and a **substantially** cylindrical middle section of reduced expandability in comparison with the end sections and the middle section diameter being smaller than the outer end section diameters and further having tapered sections connecting the first and second end sections to the middle section and extending from the middle diameter to the outer diameter. Glastra further shows (Fig. 6) the stent terminates at portions of the end sections of the balloon. The examiner is interpreting the claimed feature "selectively stiffened" in this way: to impart a particular arrangement in perform that does not change. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Since Glastra teaches the balloon is preformed into a flared arrangement, the middle can be considered to be selectively stiffened because it does not expand or flare out as does the end portions, col. 2, lines 1-5,52,53. However, Glastra does not disclose a liquid impermeable cover over the stent. Lunn teaches (Fig. 5A) a liquid impermeable cover **10** for stents, col. 5, lines 59,60,64-66, col. 6, lines 4-8. It would have been obvious to one of ordinary skill in the art to use a liquid impermeable cover such as a graft taught by Lunn with the graft catheter arrangement of Glastra et al. such that it provides a smooth surface to line the vessel wall and shield the metal from the vessel wall. Glastra does not explicitly show

the stent having "substantially cylindrical end sections" extending from the tapered sections. Lunn shows (Figs. 5C,5D) stent grafts used in repair of diseased blood vessels have the stent **ends** being substantially cylindrical to extend from tapered *sections* of the prosthesis. Thus, it would have been obvious to one of ordinary skill in the art to modify the ends to be substantially cylindrical to extend from the tapered sections of the stent of Glastra et al. per the teaching of Lunn in order to better anchor the stent graft structure in the vessel. Regarding claims 31,36,37, the structure implied in claim 31 is discussed above and the structure is fully capable of throttling blood flow.

Claims 16,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glastra et al. in view of Lunn as applied to claim 31 above, and further in view of Andrews et al. (WO 98/05377). Glastra et al. as modified by Lunn is explained supra. However, Glastra in view of Lunn do not disclose the balloon is selectively stiffened by integrating elements therein. Andrews et al. teach that balloons for expanding stents are selectively stiffened by integrating reinforcement in the balloon, which includes the middle, page 4, lines 5-7. It would have been obvious to one of ordinary skill in the art to stiffen the balloon as taught by Andrews et al. in the stent catheter balloon of Glastra as modified by Lunn such that it provides better integrity to the balloon, page 4, lines 22-24 of Andrews.

Claims 1-3,8,30-32,35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hachtman et al. (5645559) in view of Glastra et al. (EP 0779062). Hachtman et al. shows (Fig. 14) a single length stent that is deformable and flared with substantially cylindrical end sections, tapered sections and a smaller diameter middle

section to extend over a catheter. Hachtman also discloses the stent has a liquid impermeable cover, col. 6, line 24,25,28-30. However, Hachtman et al. does not disclose a catheter having a balloon being configured and arranged to expand said stent to have a first substantially cylindrical fixing portion having an outer diameter associated with fixing said stent within the vessel, a first tapered portion connected to and extending inwardly and distally from said first substantially cylindrical fixing portion, a substantially cylindrical middle portion connected to and extending from said first tapering portion, said middle portion having a middle diameter smaller than said outer diameter, a second tapered portion connected to and extending outwardly and distally from said middle portion, and a second substantially cylindrical fixing portion, having said outer diameter, connected to and extending distally from said second tapered portion, said first and second tapered portions having predetermined lengths and angles and extending from said middle diameter to a first junction of said first fixing portion and said first tapered portion at said outer diameter and a second junction of said second fixing portion and said second tapered portion at said outer diameter. Glastra teaches (Fig. 3) a balloon catheter with a balloon **6** as claimed having a first substantially cylindrical section that tapers inward to a reduced diameter section which then tapers outward to a second substantially cylindrical section. The examiner is interpreting the claimed feature "selectively stiffened" in this way: to impart a particular arrangement in perform that does not change. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Since Glastra teaches the

balloon is preformed into a flared arrangement, the middle can be considered to be selectively stiffened because it does not expand or flare out as does the end portions, col. 2, lines 1-5,52,53. It would have been obvious to one of ordinary skill in the art to use a balloon catheter as taught by Glastra et al. with the stent of Hachtman et al. such that it matches the stent construction and assures it is expanded to the set diameter. Regarding claims 2,3,8,35 Hachtman et al. disclose the covering is a "foil" of body-tolerated material, such as a polymer that is elastomeric, col. 6, lines 28-30. Regarding claims 36,37, the flared ends of the stent or "fixing portions" are configured to achieve blood throttling in the vessel and the tapered portions are configured to minimize blood turbulence in the vessel.

Claims 16,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hachtman et al. '559 in view of Glastra et al. as applied to claims 1,30 above, and further in view of Andrews et al. (WO 98/05377). Hachtman et al. as modified by Glastra et al. is explained supra. However, Hachtman in view of Glastra do not disclose the balloon is selectively stiffened by elements integrated therein. Andrews et al. teach that balloons for expanding stents are selectively stiffened by integrating reinforcement in the balloon, which includes the middle, page 4, lines 5-7. It would have been obvious to one of ordinary skill in the art to stiffen the balloon as taught by Andrews et al. in the stent catheter balloon of Hachtman as modified by Glastra such that it provides better integrity to the balloon, page 4, lines 22-24 of Andrews.

Claims 10,21,23,24,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hachtman et al. '559 in view of Glastra et al. as applied to claims

1,2,30 above, and further in view of Pinchuk et al. (EP 861638). Hachtman et al. as modified by Glastra et al. is explained supra. However, Hachtman in view of Glastra do not disclose the balloon is selectively stiffened by stiffening elements such as rings or that the cover is ptfe. Pinchuk et al. teach that stiffening the midsection or segments of the apparatus is accomplished by placing rings about the surface of the stent and can be accomplished in a secondary process such as bonding, col. 7, lines 10-16,21-24. Therefore this placement is on the balloon since the stent is on the balloon. Regarding claim 21, Pinchuk et al. teach that cover or graft material for a stent in the form of a "foil" of body-tolerated material, can include the polymer PTFE, col. 1, lines 48-50. It would have been obvious to one of ordinary skill in the art to substitute coating materials and use the well known ptfe polymer taught by Pinchuk et al. on the stent of Hachtman et al. as modified by Glastra et al. such that it is biocompatible and durable. PTFE is a well known durable material.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Glastra et al. (EP 0779062) in view of Lunn as applied to claim 30 above, and further in view of Crocker et al. (5843116). Glastra in view of Lunn is explained supra. However, Glastra as modified by Lunn fail to disclose stiffening elements bonded with the balloon. Crocker et al. show (Fig. 3) that stiffening material is used to selectively stiffen a balloon catheter to limit the expansion of the balloon in certain areas, col. 5, lines 29-49. Crocker teaches bonding is the means to attach the stiffening elements, col. 6, lines 8-10. It would have been obvious to one of ordinary skill in the art to use the teaching of Crocker et al. that stiffening material can be bonded to a balloon and place stiffening

elements on a balloon catheter of Glastra as modified with Lunn such that it assures the region of reduced expandability does not overexpand.

### *Response to Arguments*

Applicant's arguments with respect to claims 1,30 have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738